REMARKS

The Office Action dated January 15, 2003 has been read and carefully considered and the present amendment submitted to clarify the language of the claims to better define the subject invention.

In that Office Action, claims 29-31 were objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be written in the alternative. Claims 1-25 and 27-31 were rejected under 35 U.S. C. 103(a) as being unpatentable over Charlton *et al*, U.S. Patent 5,208,163 in view of Jenkens *et al*, U.S. Patent 6,423,550.

As to the objection with respect to the improper form of multiple dependent claims 29-31, it appears for Applicant's attorney's file that a Preliminary Amendment was filed in this application prior to a first Office Action where the multiple dependencies of claims 29-31 were eliminated, that is, the reference in claim 29 to "claims 26-28' was amended to refer only to "claim 26" and, in claim 31, the reference to "claims 1-18 was amended to depend only from "Claim 1" and therefore, it is believed that the objection with respect to the improper multiple dependencies has previously been corrected. If the Examiner's office file does not confirm that correction and amendment of the claims 29 and 31, it is respectfully requested that the Examiner contact the undersigned attorney by phone so that a further correction can be made by Examiners amendment or a supplemental amendment.

Accordingly, as to the prior art rejection, claim 1 has been amended to better recite a distinguishing feature of Applicant's invention so as to better define that invention over the cited references.

As not recited in claim 1, therefore, the claim states that the substrate includes at least one "throughbore" that passes "entirely through the substrate" so that such throughbore is a location, size and shape suited "for access by said automatic testing machine". As further recited, the supportive material is mounted so as to be at least

partially positioned over "said throughbore" wherein there is a sample deposition portion of the supportive material that is "within said throughbore" and further there is a description of the channel portion that is located a predetermined lateral distance away from the sample deposition portion for indicating that the sample deposition portion is "entirely wetted" so as to be used "by punching out at least a portion of the sample deposition portion". As such, the preferred embodiment of the present invention is more clearly described in the claim language.

The presence of a throughbore is described in the specification, page 3, line 20 where it is stated "Preferably said first aperture is a throughbore." and, further at page 13, line 15 *et seq*, where the first apertures are described to be "throughbores" and, therefore, there is a foundation in the specification for the newly added claim language. As to the testing apparatus, it is also stated on page 19, lines 19-21 that "In addition, the apparatus locates and punches out, or otherwise removes, the required number of samples from within the corresponding number of apertures." It is thus submitted that the present amendments to claim 1 are well supported by the specification.

As to use of the throughbore, it is best explained by describing the background of the present invention and, in particular, the procedure to which the present invention is directed.

The present invention relates to a sample collector for the collection of samples of bodily fluid, most usually blood, for transporting the sample to a remote site where the fluid, usually by then in a dry state, is taken from the collector for analysis.

Such collectors are of simple construction, intended to allow the same to be collected by a nurse, or even a non-expert, for onward transmission to a laboratory. In the case of both the present invention and the most relevant prior technology for identical purposes, the collector comprises a substrate, for example in the form of a test card or plastic holder, through which can be accessed a sample collection material, referred to in claim 1 as a "supportive material". This is typically an absorbent material such as a filter

paper or a hydrophobic membrane (see page 9 lines 5-7). The substrate is essentially non-functional, serving as a carrier and structural component.

The whole collector is transported dry (see page 2, lines 15-23) to an analysis laboratory. At the laboratory, an area is punched out including the collected sample (see page 2, line 25 to page 3, line 6). That sample is then analyzed.

In most prior art collectors, for use in this testing regime, one of more relatively large sample collection areas are provided, for example, as large areas of filter paper, with the drops of blood collected somewhere thereon. The amount of blood in a drop is likely to vary. Therefore, punching out the whole of the relatively large sample area is likely to produce a variable sample size. Accordingly, this procedure has routinely been refined so that a smaller fixed area of sample is taken, being targeted on that part of the sample collection area which is clearly wetted by the drop. This is judged either by the technician's eye or by suitable automatic imaging systems. The prior art earlier cited, such as the Ostrup patent, is a good illustration of an example of system in the particular collection and test regime to which the invention relates.

Th invention which is the subject of the present application takes an approach which is believed to be new within the specific collection and testing regime represented, for example, by Ostrup. It provides instead relatively smaller sample collection areas, such as relatively smaller areas of filter paper, which are intended to be entirely wetted by the blood sample and collection. These areas are then punched out in their entirety, obviating the need previously in equivalent systems of selecting an area stained by the blood sample at the punching stage. The substrate (i.e. the holder card) serves as a guide means for this punching step. In this way, a consistent sample is more reliably achieved.

To ensure that the sample area of the present device is fully wetted, a secondary indicating area is provided laterally spaced from the sample collection area. Blood collects on the absorbent support material and wicks outwards. When it wicks as far as this secondary area, there is provided a clear visible indication that more than a sufficiency of

blood has been collected on the main sample area (i.e. provides a clear indication that it is fully wetted).

The present invention is limited to samples which are collected as liquids and which are visible on the collector in both wet and dry states, and is therefore in practice likely to be limited to blood. Given also that the testing regime in which the present product is intended to be used relates primarily to simple mass screening, the product should also be cheap and simple, comprising for example, absorbent filter paper collection area within a sample care or plastic supporting substrate such as shown and described in the specific embodiments in the present application.

As such, it is submitted that the newly worded claim that adds the various limitations relating to the presence of at least one throughbore is readily distinguishable over the Charlton *et al* reference in view of Jenkins *et al*.

Referring to the new cited art, it can be seen that Charlton *et al* does not include a secondary metering chamber which provides an indication of the amount of blood collected in the primary chamber. The device in Charlton *et al* is not intended for use in an identical test regime to the present collector. Rather, the Charlton *et al* device is an analysis tool in itself. Blood is collected on the sample collection area and wicks down through the layers of the device to an area provided with analytical reagents to provide a test result *in situ*. The metering chamber provides an indication of when the correct quantity of blood to perform the reaction is present in the collection area.

As now recited in claim 1, however, there is an even more important distinction that relates to the presence and use of a throughbore where the automated testing apparatus is intended to punch out a portion of the sample deposition portion and which, of course, has been fully wetted by the sample as indicated by the indicator means in the channel portion. In Charlton *et al*, a blood sample from the collection area is never intended to be punched out for onward transmission so the considerations leading to provision of a metering chamber in Charlton *et al*, the considerations leading to the indication provided in the present device are not equivalent and, significantly, there is no need, or use, for a

throughbore where the supportive material is located so that the process of punching out the sample portion can be accomplished.

Clearly due to the construction of the Charlton *et al* analysis device, there is a cover layer and bottom window layer and, without those layers, the device of Charlton *et al* would be ineffective to carry out its intended purpose. The presence of those layers is totally inconsistent with the presence of a throughbore where a sample can be punched out for later analysis and thus the Charlton *et al* reference does not disclose the use of a throughbore nor would one ever be consider for the Charlton *et al* device since it would basically thwart the purpose of the analysis function of the Charlton *et al* device, a function that is nonexistent in the present collection device.

As such, there would be no reason to resort to any other reference, such as Jenkens *et al* to modify the Charlton *et al* device to add a throughbore where the sample can be punched out. Basically, even if there were such a suggestion, the Jenkins *et al* reference, again discloses a testing regime that is different from the one to which the present invention is directed. Jenkins *et al* is a saliva collector, and is intended to be transported protected in a sealed pouch rather than in a simple dry state and is not designed to be subject to the sample punching process of the specific test regime to which the current product will be subjected in practice.

Accordingly, as now recited in the newly amended claim 1, it is submitted that the claim language distinguishes the present invention over the disclosure of the cited references and an allowance of the claims in this application is respectfully solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with Markings to Show Changes Made.**"

Respectfully submitted,

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Version With Markings to Show Changes Made

In the Claims:

Claim 1 has been rewritten as follows:

1. (Amended) A test device for use in automated testing apparatus comprising: a substrate of size and shape suitable for handling by said automated testing apparatus, and including at least one [indentation or aperture] throughbore passing entirely through the substrate wherein said [indentation or aperture] throughbore is a location, size and shape suited for access by said automatic testing apparatus; and further comprising supportive material mounted on at least a part of said substrate so as to be at least partially positioned over said [indentation or aperture] throughbore; and wherein said supportive material comprises a guide means comprising a sample deposition portion that is wetted by a fluid sample, said sample deposition portion being within said throughbore and attached to a channel portion, said channel portion including an indicator means arranged therein at a predetermined lateral distance away from said sample deposition portion for indicating that the sample portion is entirely wetted so as to be used for testing by punching out at least a portion of the sample deposition portion ; wherein the positioning of the sample to be tested on said sample deposition portion of said supportive material results in excess fluid of said sample traveling along said channel portion and interacting with said indicator means to indicate that said sample deposition portion has been entirely wetted by the fluid sample so as to permit the excess fluid to travel along the channel portion and interact with the indicator means.